PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) 3086/1734 (AM 1150)

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On: February 19, 2010

Signature: /G. Peter Nichols/

Typed or printed name: /G. Peter Nichols/

Application Number	Filed
10/774,092	February 6, 2004

For: Method of Augmenting The Immune-Modulatory Activity of Standardized Echinacea Preparations

First Named Inventor Brovelli et al.

Art Unit	Conf. No.	Examiner
1655	7125	Leith

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five(5) pages may be provided.

I am the:

☐ Applicant/Inventor.

☐ Assignee of record of the entire interest.
See 37 CFR 3.71. Certificate under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

☒ Attorney or agent of record.
Registration number: 34,401.

☐ Attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34. _____.

/G. Peter Nichols/
Signature

G. Peter Nichols
Typed or Printed Name

312-321-4276
Telephone number

February 19, 2010
Date

Note: Signatures of all inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*

☒ *Total of 1 form is submitted.

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Date: February 19, 2009 Name: G. Peter Nichols Signature: /G. Peter Nichols/

3086/1734 (AM1150)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brovelli et al.

Serial No. 10/774,092

Filing Date: February 6, 2004

For: METHOD OF AUGMENTING THE IMMUNE-MODULATORY ACTIVITY OF STANDARDIZED ECHINACEA PREPARATIONS

Examiner: Patricia A. Leith

Group Art Unit No. 1655

Confirmation No. 7125

Reasons in Support of Pre-Appeal Brief Request for Review

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The claimed subject matter relates to methods for selecting a maturation stage of Echinacea plants where the method consists essentially of certain defined steps. Claims 3 and 24 are independent claims and the Final Rejection indicates that claims 3, 6-7 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, each of claims 3 and 24 requires, in part,

> selecting a maturation stage that has both: (i) a standardized concentration of about 3.26% to about 3.62% of chicoric acid as measured by high performance liquid chromatography analysis; and (ii) the highest observed level of immune-stimulatory product.

The Final Rejection states that the disclosure, as filed, does not support this limitation and concludes that the phrase "about 3.26% to about 3.62%" is New Matter. The rationale used to support this conclusion is that

> While 7 specific percent values of chichoric acid are given in Table 1, Applicants do not disclose any levels between these values, nor do they teach explicitly or implicitly that the values may be 'about' these amounts. (Final Rejection mailed Dec. 24, 2009, p. 6)

Because the rationale is legally incorrect, the conclusion relying on this rationale is also legally incorrect.

Table 1 identifies the concentration of chicoric acid for seven stages of maturation of *Echinacea*. More particularly, Table 1 provides the "mean" concentration of chicoric acid as a percentage and also provides a standard error, also as a percentage. For ease of reference, Table 1 is reproduced below (with the minimum and maximum columns being added):

	Concentration of Chicoric Acid (%)			
Stage	**Mean**	**Standard Error**	**Minimum**	**Maximum**
1 - Vegetative	3.49	0.09	3.40	3.58
2 - Hidden Bud	3.52	0.16	3.36	3.68
3 - Diminutive Bud	3.26	0.10	3.16	3.36
4 - Enlarged Bud	3.62	0.11	3.51	3.73
5 - Cone Formation	3.36	0.12	3.24	3.48
6 - Ligules Erect	3.54	0.14	3.40	3.68
7 - Ligules with Color	2.59	0.10	2.49	2.69

Two additional columns have been added to show the minimum and maximum concentration of chicoric acid if the standard error is subtracted and added to the mean value, respectively.

Considering Table 1, the mere fact that the mean concentration is provided with a standard error at least implicitly, if not explicitly, discloses levels between the recited

3.26% and 3.62% and also provides sufficient detail so that one of skill in the art would conclude that the inventor invented the claimed invention. In fact, considering the values encompassed by the phrase "about 3.26 to about 3.62%" explicitly disclosed by Table 1 above, *i.e.*, 3.26, 3.36; 3.40, 3.48, 3.51, 3.58, 3.62, 3.68, and 3.73, there can be no doubt that the Examiner's rationale supporting the conclusion of New Matter is factually flawed. Clearly, Applicants disclosed values between 3.26 and 3.62 and clearly Table 1, implicitly or explicitly teach that the values 3.26 and 3.62 are "about" 3.26 and 3.62, respectively. The rejection based on35 USC 112 should therefore be withdrawn.

The Final Rejection also states that "[c]laims 3, 6, 7 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gahler (US 6,511,683) in view of the combination of newly cited Letchamo et al., "Factors Affecting Echinacea Quality," ASHS Press, Alexandria, VA (2002), Seidler-Lozykowska et al. (2003), Dou et al. (2001 – Abstract), and Rininger et al. (2000). As an initial matter, in view of the incorrectness of the 35 USC 112 rejection, claims 23 and 25 should be allowed since they are not rejected for any other reason.

As for the rejection of claims 3, 6, 7, and 24, the rejection is based on speculation that one of skill in the art reviewing the cited art would be led to a method of selecting a maturation stage that has **both** a standardized concentration of about 3.26% to about 3.62% of chicoric acid as measured by high performance liquid chromatography analysis; **and** the highest observed level of immune-stimulatory product. The Examiner incorrectly characterizes the claim as being "directed toward selection of a particular maturation stage" (final rejection mailed Dec. 24, 2009, p. 20). This characterization

incorrectly simplifies the invention, since the claims require both a standardized concentration of chicoric acid and the highest observed level of immune stimulatory product. Because the combinations proposed by the Examiner do not teach or suggest both a standardized concentration of chicoric acid and the highest observed level of immune stimulatory product, the claims are not obvious in view of the cited art.

In short, even when each of the four references cited by the Examiner is combined, one of skill in the art is not led to the presently claimed method. Thus, despite the fact that the teachings of the cited references are like pieces of a puzzle, they do not fit together to arrive at Applicants complete method.

Applicants believe that currently pending claims 3, 6-7, and 23-25 are patentable. The Examiner is invited to contact the undersigned attorney for the Applicants at 312.321.4276 if such communication would expedite allowance of this application.

Respectfully submitted,

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